K012698

NOV 0 9 2001

510(k) Summary of Safety & Effectiveness

Submitter

Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, FL 33815

Contact

Mr. Mike Sammon, Ph.D.
Director, Research and Development
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Date

August 13, 2001

Device

- Trade Names: Vanguard Reprocessed Phacoemulsification Needles/Tips
  - ⇒ Alcon Laboratories Microtip™ and TurboSonics® Phacoemulsification Needles/Tips
  - ⇒ Allergan AMO® Proficient® Phacoemulsification Needles/Tips
- Common Name: Phacoemulsification Needle/Tip, Phaco Needle/Tip
- Classification: 21 CFR 886.4670 – Class II – Phacofragmentation system
- Product Code HQC

Predicate Devices

Respective Alcon Laboratories and Allergan legally marketed phaco needles under various 510(k) premarket notifications.

Indications for Use

As an accessory device of a compatible phacoemulsification system, the phaco needle is intended for the breaking up of a cataractous lens nucleus with simultaneous irrigation and aspiration of the emulsified fragments.

Continued on next page

510(k) Summary of Safety & Effectiveness, Continued

Device Description

A phacoemulsification needle is a component of a phacoemulsification system that utilizes ultrasound to disrupt and extract a cataract through a small incision. Ultrasonic energy combined with the mechanical action of the vibrating tip applicator (phaco tip) is applied to the cataractous lens of the eye. The lens undergoes fragmentation and emusification and is rapidly removed from the eye by aspiration.

The phaco tip is a hollow titanium needle located centrally in a handpiece with is connected via an irrigation and/or aspiration line(s) to a console for powering and controlling the functions of the phaco system. The tip is piezoelectronically oscillated longitudinally at an ultrasonic frequency of about 40,000 hertz.

Vanguard receives previously used phaco needles (only) from healthcare facilities; cleans, inspects, tests, repackages and sterilizes the devices; and returns them to the healthcare facility.

Technological Characteristics

The Vanguard reprocessed phaco needles are essentially identical to the currently marketed OEM devices. No changes are made to the currently marketed device's specifications and they possess the same technological characteristics. Performance/functional testing demonstrate that the devices are equivalent and continue to be safe and effective for their intended use. As composite materials of all VMC reprocessed phaco needles are identical to the currently marketed devices of Alcon and Allergan (titanium alloy), biocompatibility testing was not performed.

Test Data

Cleaning, sterilization and packaging validations; and functional/performance demonstrates that the reprocessed devices perform as intended and are safe and effective.

Conclusion

Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard reprocessed phacoemulsification needles/tips are substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 9 2001

Vanguard Medical Concepts, Inc.
c/o Mike Sammon, Ph.D.
Director of Research & Development
5307 Great Oak Drive
Lakeland, FL 33815

Re: K012698
Trade/Device Name: Vanguard Reprocessed Phacoemulsification Needles
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation Systems
Regulatory Class: Class II
Product Code: HQC
Dated: August 13, 2001
Received: August 14, 2001

Dear Dr. Sammon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Indications for Use

510(k) Number:

Device Name: Vanguard Reprocessed Phacoemusification Needles/Tips

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

MRB Nicholas
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012698